



suffers from primary pulmonary hypertension ("PPH") as a result of her ingestion of Diet Drugs.

I.

In PTO No. 1415, this court approved the Settlement Agreement. Paragraph 7 of PTO No. 1415 provides:

The court hereby bars and enjoins all class members who have not, or do not, timely and properly exercise an Initial, Intermediate, Back-End or Financial Insecurity Opt-Out right from asserting, and/or continuing to prosecute against [Wyeth] or any other Released Party any and all Settlement Claims which the class member had, has or may have in the future in any federal, state or territorial court.

PTO No. 1415 ¶ 7.

Under the Settlement Agreement, PPH is excluded from the definition of Settled Claims, and therefore PPH claims are not subject to the release and bar provisions of the Settlement Agreement. Settlement Agreement § VII.B. The definition of PPH under the terms of the Settlement Agreement, however, is rigorous. Plaintiffs claiming a diagnosis of PPH must satisfy a three-part definition. Only the second prong of the definition is in controversy here, which requires putative PPH plaintiffs to provide, among other things:

Medical records which demonstrate that the following conditions have been excluded by the following results:

- (a) Echocardiogram demonstrating no primary cardiac disease including, but not limited to, shunts, valvular disease (other than tricuspid or pulmonary valvular insufficiency as a result of PPH or trivial, clinically insignificant left-sided valvular regurgitation), and congenital heart disease (other than patent foramen ovale)....

Settlement Agreement § I.46.a.(2)(a).

We previously have stated that PTO No. 1415 requires "this court to decide if there is a genuine issue of material fact as to whether plaintiff suffers from PPH. If no such issue exists, this court will enjoin the plaintiff from going forward. Otherwise, it is a matter for the trial court." PTO No. 3699 at 4 (July 6, 2004).

## II.

In the present motion, Wyeth argues that Ms. Randow does not satisfy the definition of PPH under the Settlement Agreement and therefore cannot pursue her state court action. Specifically, Wyeth contends that Ms. Randow's medical records demonstrate a shunt and a congenital heart defect, namely, an

atrial septal defect.<sup>2</sup> In support, Wyeth refers to the report of a November 21, 2008 cardiac catheterization, which concludes that Ms. Randow suffers from a "[s]ignificant left-to-right shunt with the oxygen step-up at the SVC level, suggestive of a sinus stenosis [atrial septal defect] with partial anomalous pulmonary venous return." In addition, Wyeth notes that a November 21, 2008 transesophageal echocardiogram revealed "[e]vidence of ostium secundum atrioseptal defect." Although Ms. Randow underwent surgery to close her atrial septal defect, Wyeth contends that she continues to suffer from a residual left-to-right shunt.

Ms. Randow relies on two submitted echocardiograms dated January 14, 2009 and January 18, 2009, each of which in her view demonstrate "clearly and unmistakably" that she does not have a shunt or other congenital heart defect. Ms. Randow further asserts that the checklist completed by George G. Miller, M.D. and a right heart catheterization performed on October 18, 2011 both confirm that she does not have a shunt or an atrial septal defect.

---

2. Wyeth contends, and Ms. Randow does not dispute, that an atrial septal defect is considered a congenital heart defect.

According to Wyeth, Ms. Randow's post-surgery echocardiograms demonstrate that, although she underwent surgery to repair her shunt and atrial septal defect, the surgery has not been entirely successful because the septal occluder device, which is used to plug a hole in the heart, has shifted. As a result, the shunt persists. Specifically, Wyeth refers to a number of post-surgery echocardiograms:

- April 3, 2009 echocardiogram: "An Ampatzer [sic] [atrial septal defect] occluder is noted across the atrial septum. A small portion of the anteroseptal rim of the left atrial Ampatzer [sic] disc is prolapsing through the secundum [atrial septal defect]. There is resulting mild continuous left-to-right shunt noted by color Doppler exam between prolapsed segment and anterseptal [atrial septal defect] rim.
- March 9, 2010 echocardiogram: "Status post Amplatzer with evidence of continuous Left -to- Right shunt."
- September 7, 2011 echocardiogram: "There is evidence of atrial septal defect occlusion device

(atrial septal defect, [atrial septal defect])  
noted across the interatrial septum. There is  
evidence of color Doppler flow across the  
interatrial septum, suggesting residual shunting."

III.

As stated above, the Settlement Agreement requires putative PPH plaintiffs to provide, among other things, medical records that exclude a number of identified conditions, including primary cardiac disease. Settlement Agreement § I.46.a.(2)(a). The Settlement Agreement defines primary cardiac disease to include "shunts, valvular heart disease (other than tricuspid or pulmonary valvular insufficiency as a result of PPH or trivial, clinically insignificant left-sided valvular regurgitation), and congenital heart disease (other than patent foramen ovale)[.]" Ms. Randow simply cannot satisfy the definition of PPH set forth in the Settlement Agreement.

Importantly, Ms. Randow's medical records demonstrate, and she does not contest, that she has congenital heart disease in the form of an atrial septal defect. Second, although Ms. Randow had surgery to repair the shunting that results from her congenital heart disease, the shunting has persisted post-

surgery. Both shunting and congenital heart disease are specifically identified by the Settlement Agreement as primary cardiac disease.

Moreover, the representation of Dr. Miller in the Primary Pulmonary Hypertension Checklist does not change this result. The part of the PPH definition at issue here expressly requires that a putative PPH plaintiff establish, through an echocardiogram only, the absence of primary cardiac disease. We must apply the Settlement Agreement as written. Thus, Dr. Miller's checklist is not relevant to determining whether Ms. Randow can satisfy Part 2(a) of the definition of PPH set forth in the Settlement Agreement.

Ms. Randow has not raised a genuine issue of material fact to support her claim that she suffers from PPH. Accordingly, the motion of Wyeth to enforce the Settlement Agreement so as to bar her from proceeding with her state court action will be granted.